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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PATEL, YOGESH P	
ART UNIT	PAPER NUMBER
3732	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/759,811	MILES ET AL.	
	Examiner	Art Unit	
	YOGESH PATEL	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 11-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 11-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/17/2008 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 5, 11 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer et al. (US 5,728,046) in view of Mathews et al. (US 6,206,826):

Mayer discloses a surgical retractor system (see Figures 1-2) for accessing a target site within a spine (i.e. column 1, lines 31-34), wherein said system comprises a primary retractor assembly having a handle assembly (i.e. frame assembly, 5) and three separate retractor blades (7,18,19) removably coupled thereto. This handle assembly is adapted to move each retractor blade between open and closed positions via holders (8,9) and corresponding holding arms (10,11). The overhead view of Figure 2 shows the system in an open position wherein each retractor blade is positioned generally away

from one another. However, when holding arms (10, 11) are extended longitudinally toward the center of the assembly, the system reverts back to a closed position wherein each of retractor blades are generally adjacent to on one another. Mayer further discloses a supplemental retractor assembly having an arm (i.e. 20/21) with a fourth retractor blade (i.e. 32) removably coupled to said arm (i.e. via threaded spindle 29 and corresponding nuts 30,31). This arm (20/21) is shown coupled to the handle assembly (5) of the primary retractor assembly in Figures 1 and 2. The fourth retractor blade (32) is adapted to be introduced into the surgical site as shown in Figures 1-2, and which is capable of being moved to expand the worksite via threaded spindle (29) and corresponding nuts (30,31). Additionally, the system of Mayer includes at least one shim member (i.e. 36) adapted to be coupled to one of the retractor blades (see Figures 1-3), wherein said shim member includes a contiguous extension which is dimensioned to extend past the retractor blade as shown (see Figure 3). Mayer fails to disclose the use of a distraction assembly in conjunction with the aforementioned retractor assembly.

Mathews teaches a system for accessing a surgical target site comprising using a distraction assembly (i.e. D) in conjunction with a retractor assembly (see also Figure 21), wherein said distraction assembly is adapted to create a distraction space in a vertebral work site (column 11, lines 28-34). The retractor assembly shown by Mathews additionally includes four retractor blades (i.e. 10) which can be introduced simultaneously over the distraction assembly to the surgical target site (i.e. see Figures 21). Therefore, it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to modify the system of Mayer by including the distraction

assembly as taught by Mathews in order to simultaneously distract the affected vertebral disc space while also retracting said space. With respect to claim 3, the assembly of Mathews can include a plurality of sequential dilators (column 10, lines 59-65). Further, it would have been obvious to one having ordinary skill in the art at the time of the invention to use retracting blades in any order (e.g. using three blades for retracting as in fig. 2 of Mayer, and using forth blade to retract the side of a working site) since it would depend on the individual cases.

Further, the Examiner notices the usage of functional/intended use language (e.g. adapted to) in the claims. It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138. Furthermore, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Claims 2 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer in view of Mathews, as applied to claim 1 above, and further in view of Luque (US 4,913,134):

Mayer and Mathews disclose the system as previously described in detail. Additionally, Mathews discloses the distraction assembly shown in Figure 21 is capable of being slideably passed over a guidewire if desired (column 10, lines 52-58). Mathews fails to disclose that the guidewire is a kirschner wire.

Luque teaches a spinal fixation system which utilizes a guidewire (17) that can be a kirschner wire (column 3, lines 59-61). Therefore, it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to modify the guidewire of Mathews by using a kirschner wire as taught by Luque in order to provide a fixation means to the bone (Examiner further notes that a k-wire is a type of guidewire).

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer in view of Mathews Luque, as applied to claim 2 above, and further in view of Arthur (US 972,983):

Mathews discloses the dilator as previously described above, but fails to specify that the dilator is a split-type dilator. Arthur, however, teaches a split dilator (i.e. see Figure 7-8). Therefore, it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to modify the dilator of Mathews by utilizing a split dilator as taught by Arthur in order to increase efficiency by making operation of the device easier (column 1, lines 14-17).

Claims 6-8, 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer in view of Mathews, as applied to claim 5 above, and further in view of Underwood et al. (US 2001/0056280):

Mayer and Mathews disclose the system as previously described above, but fail to show the assembly includes stimulation electrodes.

Underwood, however, teaches a retractor for use in spine surgery (i.e. 278), wherein said retractor includes a stimulation electrode (112) positioned near a distal end of the distraction system (see Figure 13). Therefore, it would have been obvious to one

having ordinary skill in the art at the time of Applicant's invention to include a stimulation electrode with the retractor of Mayer in order to move, contract, and otherwise modify the tissue structures at the surgical site by using a an electric stimulus as taught by Underwood. As to claims 7-8 and 20, the system can further comprise a control unit which is capable of electrically stimulating the electrode, sensing a response from stimulation of a nerve or muscle, and communicating to a user (i.e. paragraphs 0058 and 0071). As to claim 13, the control unit of Underwood can comprise a display (i.e. 32).

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer in view of Mathews and Luque, as applied to claim 2, and further in view of Kraus (US 4,611,597):

Luque discloses the use of a k-wire as previously described, but fails to specify that said k-wire further comprises a stimulation electrode.

Kraus, however, teaches the use of a k-wire for insertion into bone, in which said k-wire further includes an electrode (column 3, lines 55-63). Therefore, it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to modify the k-wire of Luque by adding an electrode to its tip in order to provide a means for providing an electric stimulus for stimulating bone growth as taught by Kraus.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer in view of Mathews and Underwood, as applied to claim 7 above, and further in view of Shin et al. (US 4,226,228):

Underwood teaches the use of stimulation electrodes on the system as previously described, but fails to show the assembly includes a button on the handle.

Shin teaches a surgical retractor (i.e. 10) which includes a handle (i.e. 14) with a button (i.e. 18) on it. Therefore, it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to modify the previously detailed retractor system by including a button on the handle as taught by Shin in order to allow for the practitioner to easily access it during a surgical procedure.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer in view of Mathews and Underwood, as applied to claim 7 above, and further in view of Streeter (US 6,273,905):

Underwood teaches the system as previously described in detail above, but fails to show the control unit comprises a touch-screen display.

Streeter teaches a method for performing spinal surgery in which a control unit (i.e. 14) with a touch screen (i.e. 48) is used. Therefore, it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to modify the system of Underwood to include a touch screen in communication with the control unit in order for the practitioner to easily input data as taught by Streeter (column 4, lines 49-53).

Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer in view of Mathews, as applied to claim 16 above, and further in view of Schrom et al. (US 7,047,082):

Mayer and Mathews disclose the surgical access method as previously described above, but are silent as to the step of performing neuromonitoring.

Schrom teaches the step of neurostimulation to the spinal area using a neurostimulation lead, wherein said lead can be used for neuromonitoring (column 4, lines 1-8). Therefore, it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to perform the step of neuromonitoring as taught by Schrom during the method steps of Mayer and Mathews in order to help diagnose neurological disorders. Schrom is silent about the neuromonitoring being EMG response. However, the term neuromonitoring employs various recordings such as EEG, EMG, ABR etc.

Response to Arguments

Applicant's arguments filed 09/17/2008 have been fully considered but they are not persuasive. Applicant argues that Mayer is silent about limitation "a primary retractor assembly having a handle assembly...second and third retractor blades being positioned generally away from one another" and argues that the retractor blades 7, 18, 19 are positioned generally adjacent to one another is neither shown or described in Mayer. The Examiner respectfully disagrees because the handle assembly is capable of (or adapted to) moving first, second and third blades between closed position and open position due to arms 10 and 11. Further, based on the applicant's arguments, it appears that there is confusion abut the term "adjacent." A dictionary defines that term as "lying near or close; neighboring." Thus, the claimed limitation is met.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YOGESH PATEL whose telephone number is (571)270-3646. The examiner can normally be reached on 8:00 to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriguez can be reached on 571-272-4964. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/YOGESH PATEL/
Examiner, Art Unit 3732

/Cris L. Rodriguez/
Supervisory Patent Examiner, Art Unit 3732